IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

RODGER R. ANSTETT, et al.,

Plaintiffs,

v.

STATE OF OREGON, et al.,

Defendants.

Civil No. 01-1619-BR

ORDER

BROWN, Judge.

The Court GRANTS the Parties' Joint Motion to Implement Guidelines and Extend Review Period (#188). Accordingly, IT IS HEREBY ORDERED as follows:

1. The Oregon Department of Corrections ("ODOC") shall implement the ODOC Hepatitis C (HCV) Treatment Guidelines (the "Guidelines") as revised by the Medical Review Panel ("MRP") and attached hereto as Exhibit 1.

2. The Oregon Department of Justice, together with ODOC, shall conduct an in-service training session on implementing the Guidelines for ODOC medical health care providers on or about June 23, 2006.

3. The MRP chart review period, as described in §4(a) of the Parties' Settlement and Release Agreement (Doc. #142), shall be extended to December 31, 2006, to allow the MRP to conduct another random chart audit of up to twelve inmate charts from a variety of ODOC institutions for the purpose of assessing ODOC medical care provider compliance with the Guidelines. If the MRP finds 90% of the charts reviewed indicate compliance with the Guidelines, ODOC will be deemed in compliance. The parties shall notify the Court not later than January 31, 2007, of the results of the MRP chart review. At that time, the Court will consider any request for additional chart review.

IT IS SO ORDERED.

DATED this 4th day of August, 2006.

ANNA J. BROWN
United States District Judge

OREGON DEPARTMENT OF CORRECTIONS

SUBJECT: **MEDICAL GUIDELINES FOR HEPATITIS C EVALUATION AND TREATMENT - 2004**

FROM: Hepatitis C Review Panel

DATE: August 2004

The following guidelines are provided to assist patients, physicians and the ODOC health system to make appropriate decisions regarding the diagnosis and treatment of Hepatitis C. The guidelines have been arrived at after review of medical evidence, existing Oregon ODOC guidelines, other correction system guidelines and input from Oregon Corrections and inmate advocacy groups. A three physician panel was commissioned to write these guidelines.

Only 5% to 20% of patients with viral hepatitis C develop any liver complication. A much higher percentage carry the virus and can transmit it particularly if intravenous drug use continues. Medication treatment takes 6-12 months and has significant side-effects. Successful treatment results in eradication of the virus but does not confer immunity to subsequent viral exposures. Improved clinical outcomes (death, liver failure, need for transplant) have not yet been demonstrated given the long latency period and small proportion of patients advancing to liver failure. Successful treatment can occur during any period during the infection.

Appropriate medical screening of candidates must occur before initiating this therapy. Any candidate for therapy should understand before treatment, that testing is required and liver biopsy may be required. The course of hepatits C and the likelihood of progression to advanced liver disease vary greatly among individuals over time, and the extent of liver injury is often difficult to determine without a liver biopsy. Treatment and liver biopsy are not without risk, and these risks must be weighed against the probable course of untreated Hepatitis C. The side effects of interferon and ribavirin, the length of treatment and the need for monitoring must be fully discussed with patients. If there are reasonable documented concerns about a patient's ability to comply with the treatment, and reduction of risk behaviors, treatment should not be initiated. A major objective of treatment is to stop the transmission of the virus in the Corrections population. If there is any indication of active intravenous drug use, any substance abuse or use of needles for other purposes, the likelihood of reinfection is high and proceeding with treatment is contraindicated.

Deciding on treatment of patients with Hepatitis C can be a complicated task due to many factors. These guidelines have been developed to help discern patient eligibility for treatment and establish some criteria for the use of pegylated interferon and ribavirin in the treatment of

EXHIBIT 1

chronic Hepatitis C within ODOC. These are guidelines only, each individual's care should be decided on a case-by-case basis using professional knowledge and judgement within the physician-patient relationship. Comments are encouraged since it is likely research will continue to provide information changing these suggestions.

Hepatitis C decision making issues are more complex because of the individual's need for informed consent versus the vulnerability of the populations to a transmissible agent. We have tried to take these factors into consideration in our recommendations.

PATIENT ELIGIBILITY CRITERIA:

Patients already on interferon, or interferon and ribavirin at the time of initiating these guidelines or at the time of entry into custody will be maintained on the drug if tolerated.

For all other inmates education concerning hepatitis risks will be provided in the context of communicable disease education and those at risk offered screening for hepatitis and appropriate medical evaluation. The decision to treat will be made on an individual, case by case, basis with the individual's medical information, evidence on treatment efficacy and population risk in mind.

Hepatitis C Evaluation, Testing, and Treatment Guidelines

1 All inmates are provided intake screening (See Attachment 1, ODOC Intake Screening Forms) that provides education regarding health issues relevant to them and the population they reside in, including risk factors for hepatitis C acquisition. After intake screening if patient requests Hepatitis C testing or treatment, refer to CTS/HIV counselor (Blood Bourne Pathogen counselor) who will initiate pre-test counseling, and evaluate risk factors. After counseling and risk factor discussion this counselor will make inmate aware of the test request process. Diagnostic evaluation other than liver biopsy should be completed within 90 days of the date of the inmate's initial request for testing. Assuming informed consent is provided by the inmate the counselor will have an HIV test, and/or Hepatitis Viral marker panel (at least anti-HCV, anti-HBc, HBsAg) drawn as indicated, and do post-test counseling about the test results. (Note that patients having hepatitis C testing should have HIV test results due to similar risk factors, and importance of HIV status to the work-up and treatment of Hepatitis C). All positive test results will be brought to the attention of Health Services for interpretation and action as warranted. Chronic viral infection must be verified. A signal to cutoff (S/C) ratio of the EIA >3.8 is sufficient to diagnose HCV infection. If the S/C ratio is below the cut off additional confirmatory testing is necessary, such as RIBA or HCV RNA testing.

2. If negative HCV antibody test & Normal liver enzymes-- no work-up or follow up needed.

3. If negative HCV antibody test & Elevated liver enzymes-- work up abnormal findings.

4. If positive HCV antibody test, medical evaluation will be offered and if the patient consents, Health Services will schedule a practitioner appointment, order a complete chemistry panel and CBC, and will enter the patient into Inmate Health Plan, Special Needs - Hep C .

5. All patients with chronic HCV infection should be vaccinated for Hepatitis A and B after appropriate informed consent.

6. Evaluation of patients with positive HCV test results includes a history and physical examination seeking evidence of signs/symptoms of liver disease and other major medical illnesses, complete chemistry panel, and CBC.

   A. Positive HCV antibody test & normal liver enzymes–

      I. No clinical evidence of liver disease (such as evidence of cirrhosis). Enroll patient in "Hepatitis C Special Needs" for tracking purposes, repeat a complete chemistry panel every 6 months for 18 months. If persistently normal liver enzymes and no other evidence of liver disease then counsel the patient that there is no evidence that a patient with consistently normal enzymes is improved by interferon treatment. Repeat complete chemistry panel annually thereafter.

      II. If normal enzymes but other clinical evidence of liver disease (such as evidence of cirrhosis), initiate evaluation according to guidelines. Patients with signs of cirrhosis should be personally evaluated by a specialist in liver diseases and thereafter managed in consultation iwth the specialist in liver disease.

   B. Positive HCV antibody test & elevation of ALT -- Enroll patient in "Hepatitis C Special Needs". If patient requests treatment evaluation and after appropriate informed consent continue work-up as per guidelines—see below. If evidence of cirrhosis refer to outside specialist.

   C. Hepatitis C patients who are also positive for HIV should be referred to an HIV specialist.

7. Evaluate if patient has more than 12 months left within ODOC to complete evaluation and full course of treatment. If less than 12 months inform patient of status of workup, provide records of tests and suggestions regarding appropriate source of continued evaluation at the time of discharge.

8. Medical Contraindications. Contraindications should be weighed with the long latency of the disease in mind. Patients should be treated at a time optimal for successful treatment, minimal risk of side effects and appropriate use of resources.

A. Absolute contraindications

i. Clinical signs of decompensated cirrhosis

- Jaundice or elevated bilirubin (greater than 1.5 except for Gilbert's disease).
- Ascites
- Decreased platelets< 60,000
- Increased protime; INR > 1.5 (unless on Coumadin)
- Decreased albumin< 3.5
- Absolute neutrophils < 1,500 or WBC<3,000
- Active or history of Hepatic encephalopathy

ii. Medical Contraindications

- Active thyroid disorder
- Cancer within 5 years (except adequately treated basal or squamous cell cancer of the skin)
- Solid organ Transplant recipient (except cornea and hair transplant)
- Pregnancy or likely pregnancy (Ribavirin is HIGHLY TERATOGENIC)
- Major Medical Conditions worsened by anemia (especially when using ribavirin) e.g., angina, hypoperfusion states, CHF, etc., creatinine>1.5, hemoglobinopathies (expect a 2gm/dl drop in hemoglobin in the 1st month.)
- Other conditions such as COPD, seizure disorder, significant active cardiovascular conditions (eg., angina, CHF, recent MI, uncontrolled HTN, significant arrhythmias), immunologically mediated diseases (eg., inflammatory bowel disease, rheumatoid arthritis, ITP, SLE, severe psoriasis, autoimmune hemolytic anemias), and poorly controlled diabetes mellitus
- Laboratory Tests
  - Hgb<12 (Females) <13 (Males)
  - Platelets < 80,000
  - Bilirubin greater than 1.5 (except for Gilbert's disease).
  - Absolute neutrophils < 1,500 or WBC<3,000

iii. Evidence of drug or alcohol abuse issues in the past 6 months

iv. Age > 60 or <18

v. Mental health

- Current Major Depression, poorly controlled

- Significant suicide attempt within past 5 years
- Major Mental Illness present and poorly controlled.
- Recent poorly controlled aggressive behavior.

B. Relative Contraindications:
(Patients with these conditions should be carefully evaluated before considering therapy. Patients with stage 2 fibrosis and any of theses conditions may not be appropriate for interferon-based therapy)

i. Medical

- Stable cardiac disease

- Major Medical illness poorly controlled
- Life expectancy less than 10 years
- Evidence of prior medical non-compliance

ii. Mental Health

- Hx of Major Depression or suicide attempt

- Other psychiatric conditions such as a history of schizophrenia, bipolar or other serious mental illness.

C. Uncorrected risk factors as contraindications

Drug or Alcohol use/abuse (self report, positive drug screen, possession, rule violation) or a new tattoo (DOC specific) within the prior 6 months is a contraindication to medication treatment for Hepatitis C, but is not a contraindication for work up or evaluation.

If there is any medical or criminal history of substance abuse within 2 years, the inmate must be presently active in drug/alcohol recovery (including AA or NA) for at least 1 month. The involvement in drug/alcohol recovery programs may be simultaneous with the workup or evaluation. The workup and/or evaluationn for HCV treatment shall not be delayed because the patient is completing any substance abuse treatment program. Drug or alcohol relapse is an absolute indication for termination of treatment. Given the evaluation process will likely take 90-120 days and treatment will take 6-12 months it should be clear to patients that they must commit to active treatment through this entire period in order to successfully complete the diagnosis and treatment process. Failure to participate in alcohol and drug treatment anytime during the course of the diagnosis and treatment process is an indication for treatment termination.

9. Have patient review "Hepatitis C Treatment Contract". Inmate may be subject to random alcohol and drug testing and inmate will maintain participation in a drug and/or alcohol rehabilitation program if there is any medical or criminal history of substance abuse. Possession or use of alcohol or non-prescribed drugs or a positive random alcohol and drug testing or fresh

tattoos or equipment will result in removal from Interferon/Ribavirin therapy. Patient must agree to contract to proceed. See Attachment 2

10. If for medical or other reasons patient is not eligible for treatment, no further evaluation will be necessary until or unless the contraindications resolve. Routine follow up to assess contraindications should occur at appropriate intervals. If contraindications do resolve the patient should be re-evaluated for treatment. Patient should receive summary of testing done, reason for treatment contraindication and education regarding next steps given contraindication.

11. If there are no contraindications to treatment and a liver biopsy and or treatment with interferon and ribavirin is considered, a physician must give counseling about the risks and difficulty of liver biopsy as well as interferon treatment, or combination therapy.

12. After informed consent, proceed with additional testing. If not already done, baseline labs to include: CBC, complete chemistry panel, TSH with reflex, anti-nuclear antibody (ANA), anti-smooth muscle antibody (ASMA), ferritin, percent iron saturation, chest x-ray for baseline, EKG is over the age of 45, abdominal ultrasound, pregnancy test for women, review of material relevant to mental health and corrected/uncorrected risk factors. (See Attachment 3-- work sheet.)

13. If the above studies do not reveal a contraindication to interferon-based therapy proceed to HCV genotyping and quantitative viral count by RNA PCR. Determine estimate of duration of disease.

14. If the above evaluation reveals evidence of cirrhosis:

A liver biopsy is not indicated
Patients with decompensated cirrhosis should be referred to a specialist for further evaluation
Patients with compensated cirrhosis may be treated with interferon-based therapy in conjunction with a specialist.

Follow general measures guidelines for cirrhosis

The noninvasive diagnostic phase of the evaluation is completed here and should be done within 90 days after the latter of the patient's request for testing or their arrival at their receiving center.

This standard is met if 90% of patients meet the standard
Patients should be made aware of ODOC evaluation findings, recommendations and plan within 30 days. This benchmark is met if 90% of patients meet the benchmark time frame.

15. If the above evaluation reveals evidence of cirrhosis:

A. A liver biopsy is not indicated
B. Patients with decompensate cirrhosis should be referred to a specialist in liver diseases for further evaluation.
C. Patients with compensated cirrhosis maya be treated with interferon-based therapy in conjunction with a specialist in liver diseases.

16. If virus genotype 2 or 3 refer for treatment, or refer to Hepatitis C Interest Group (see below) for review if patient felt to be exception. No biopsy is needed for most genotype 2 or 3 patients. Unless risk factors are present treatment should proceed.

17. If genotype 4, proceed with treatment if patient will be available for treatment for 18 months. If not available provide patient with copies of records and suggest resource for further evaluation and treatment once discharged. No biopsy needed for most genotype 4 patients. Refer exceptions to Hepatitis C Interest Group for review.

The MRP proposes that ODOC organize a Hepatitis C Interest Group composed of ODOC practitioners with experience and interest in the evaluation and treatment of Hepatitis C patients. This Interest Group should include or have access to a hepatologist or gastroenterologist experienced in the treatment of Hep C patients. The Group would provide a quality assurance function to the Hepatitis C diagnosis and treatment process. The Group would have two objectives:

- Monitor the guideline process providing approval for exceptions to the guideline when appropriate.
- o Supervise the treatment of Hepatitis C patients. Currently in the community all Hep C patients are treated by specialists or primary care doctors experienced in the treatment of Hepatitis C.

The Interest Group should function by consensus. Records should be kept regarding their decisions.

18. If patient genotype 1

- Proceed with evaluation if patient will be available for treatment over next 18 months. If not available provide patient with copies of records and suggest resource for further evaluation and treatment once discharged.
- If patient has been infected for less than 5 years refer to Hepatitis C Interest Group for review regarding treatment. Recently infected patients have a higher reponse rate to treatment.
- If patient has been infected for 5-15 years (5-10 years if history of alcohol abuse) observation without therapy is reasonable. The risk/benefit of biopsy/treatment in this patient group should be assessed annually. If the patient or provider feels strongly that treatment is indicated then case should be referred to the Hepatitis C Interest Group for review.
- For patient with longer infection (>15 years or >10 years if significant alcohol history) or

with unknown duration refer to Hepatitis C Interest Group for review regarding biopsy.

- If patient is a candidate for liver biopsy, have patient review informed consent about liver biopsy. Refer case to Hepatitis C Interest Group for review regarding biopsy and treatment.
- After biopsy is complete refer Biopsy findings (done within five years before start of medication) and case information to Hepatitis C Interest Group.

· Prior to Hepatitis C Interest Group referral confirm information summarized in Hepatitis C Evaluation Worksheet—Attach

Current Term	Old Term	Grade/Stage	Knodell Score*	Recommendations
Mild liver disease	Chronic persistent	Stage 1	3-6	Monitor–may not be progressive disease
Moderate liver disease	Chronic Active	Stage 2	7-8	Depending on other characteristics monitoring or interferon based therapy may be recommended
Severe Liver Disease	Severe Chronic Active	Stage 3	9-11	Recommend interferon based therapy
Advanced - Cirrhosis Compensated		Stage 4	12+	INF/RBV may improve, offer in conjunction with GI specialist.
Decompensated cirrhosis		Stage 4	12+	INF/RBV unlikely to improve care and is not recommended.

* Knodell score is a histopathologic staging system

Among patients with duration of infection greater than 15 years duration, INF/RBV is not indicated in individuals with Stage I fibrosis. Some physicians have suggested re-biopsy in 5-10 years as an alternative, and it is certainly reasonable when considering an individual with stage 1 fibrosis to maximize the likelihood of success.

INF/RBV is controversial in individuals with Stage 2 fibrosis, and should be weighed within the context of the individual medical case. (For example a patient who is Grade 4 and Stage 2 after only 5 years of infection with very elevated ALTs, no medical contraindications and highly motivated who has 15 years with ODOC, may be considered differently than a patient who is Grade 1 and Stage 2 after 30 years of infection, low ALT levels, who has some relative contraindications, does not seem motivated and is leaving ODOC in 19 months.) Given the evidence of slow progression from one stage to another (some say an average of 10 years between stages) some physicians have suggested re-biopsy in 5 years as an alternative, and it is certainly reasonable when considering an individual with stage 2 fibrosis to maximize the likelihood of success.

INF/RBV is most clearly indicated for consideration for individuals with Stage 3 fibrosis with any degree of inflammation, who meet the other criteria.

Liver biopsy should be completed within 60 days of the completion of noninvasive diagnostic testing or 150 days after the latter of the date of patient request for evaluation or their departure from orientation/intake center.

This standard is met if 90% of patients meet the standard

19.All patients should be treated with pegylated interferon and ribavirin based on response rates below.

Sustained Response Rates

	Interferon	PegInf	Inf +RBV	PegInf +RBV
Genotype 1	6-10%	14%	33%	42%
Genotype 2 or 3	29%	40%	75%	76-88%

Data on SVR from multiple sources including: Fried et al.; Manns et al: Lindsey et al; McHutchinson et al.; product inserts

Treatment should be supervised by the Hepatitis C Interest Group.

Patients not requiring a biopsy should be aware of treatment options and ODOC recommendation regarding treatment within 30 days of completion of noninvasive diagnostic testing or 120 days from the

latter of the date patient requested testing or their departure from intake/orientation center. (90 days for diagnostic testing, 30 days for treatment options)

This standard is met if 90% of patients meet this standard.

Patients requiring a liver biopsy should be aware of treatment options and ODOC recommendations regarding treatment within 30 days of completion of liver biopsy or 180 days from the latter of patient request for testing or their arrival at receiving center. (90 days for diagnostic testing, 60 days for liver biopsy, 30 days for treatment options).

This standard is met if 90% of patients meet this standard.

Benchmark Timeframes

	Maximum Time
Non-invasive W/U	90 Days
Tell Plan Biopsy/NO Biopsy	30 Days
Biopsy	60 Days
Bipsy Results Plan	30 Days

Treatment Dosage Options for Chronic Hepatitis C					
Medication	Dosage	Baseline tests	Monitoring	Toxicities	Comments
Pegylated interferon –	Peg-Intron® (1.5mcg/kg/wk SC) <40 kg= 50 mcg 40-50kg=64mcg 51-60kg=80mcg 61-75kg=96mcg 76-85kg=120mcg >85kg=150mcg Pegasys® 180 mcg/wk SC	History and physical Liver enzymes Liver function CBC, diff, plts Creatinine/BUN Thyroid function Hep B status HIV status HCV genotype HCVRNAquantitative Mental health evaluation Risk behavior hx evaluation Duration of infection CBC, diff, plts Pregnancy tests	Every 2 weeks x2 then monthly: CBC, diff, plts Chem panel, (ALT, Cr, BUN, Alb. Etc.) Depression Pregnancy test monthly as indicated. MH evaluation as indicated. Quant. HCV RNA at 12 wks if genotype 1. Qualitative HCV at 24 wks.	Fever Fatigue Myalgia Psychiatric (rage, confusion, depression) Bone marrow suppression Thyroid dysfunction Renal failure	See "contraindications" Not for use in decompensated cirrhosis.
Ribavirin with Peg-Inf	Genotype 2 or 3 400 mg PO BID Genotype 1and 4 – <75kg=1000mg qd >75kg=1200mg qd			Hemolysis (5%-10% decrease in HCT is expected)	Ribavirin dosage varies by weight.

20. Duration of Treatment:

- For genotype 1 (la or lb), administer antiviral therapy for 12 weeks and check quantitative HCV RNA assay. A minimum 2 log decrease in viral load after 12 weeks of treatment predicts a sustained viral response (SVR) and warrants continued treatment for another 36 weeks (total 48 weeks course of treatment). Antiviral therapy should be discontinued if HCV RNA levels do not adequately decline after 12 weeks of treatment.

- For genotypes 2 and 3, administer antiviral therapy for 24 weeks in all patients unless complications develop.

- For genotype 4, minimal therapy data is available for this genotype. However, some data suggests that treatment success is almost as high as with genotype 2 and 3. These studies

maintained therapy for 48 weeks. Therefore treatment algorithm should be the same as for genotype 1.

At the end of treatment, check a qualitative HCV RNA assay to determine treatment response. Follow-up qualitative HCV RNA assays should be obtained 24 weeks after the completion of therapy. Effective antiviral therapy results in a sustained viral response (SVR), defined as the absence of detectable HCV RNA in the serum measured by a qualitative HCV RNA assay with a lower limit of detection of 50 IU/ml or less at 24 weeks after the end of treatment.

21. Therapy Monitoring:

See attached monitoring chart—Attachment 4

22. Cytopenia management

See attached cytopenia management chart---Attachment 5

Attach 3

Hepatitis C Evaluation Worksheet

Initial Screening Information			Date
Blood Borne Pathogen Counseling completed?	❑ Yes	❑ No	
HIV testing done?	❑ Yes	❑ No	
HCV antibody positive?	❑ Yes	❑ No	
Time left to serve greater than 18 months for genotype 1 and 4, 12 mos for 2 and 3?	❑ Yes	❑ No	

Medical Evaluation, as indicated					Date
History and Physical for indications of disease status			❑ Yes	❑ No	
Evidence of decompensated liver disease or clinical evidence of cirrhosis, e.g., ascites, hx of hepatic encephalopathy, hx of esphogeal varices, etc.			❑ Yes	❑ No	
HIV/AIDS (HIV Ab positive)?			❑ Yes	❑ No	
Major Medical Illness poorly controlled, e.g. diabetes, ASCVD, angina, COPD, thyroid, HIV, MH, cancer, autoimmune disorder, etc.			❑ Yes	❑ No	
LABS -	Abnormal values		❑ Yes	❑ No	
ALT levels / Dates		Bilirubin Elevated >1.5?	❑ Yes	❑ No	
		Albumin <3.5?	❑ Yes	❑ No	
		Protime INR > 1.5?	❑ Yes	❑ No	
		HCT/Hgb Abn?	❑ Yes	❑ No	
		WBC< 3000 or ANC<1500?	❑ Yes	❑ No	
		Platelets < 80,000?	❑ Yes	❑ No	

		TSH Abn?	❑ Yes	❑ No	
		Creatinine >1.5?	❑ Yes	❑ No	
		HepBs Ag Positive?	❑ Yes	❑ No	

Mental Health Considerations			Date
Evidence or history of suicide ideation and/or suicide attempt?	❑ Yes	❑ No	
History of severe psychiatric disorder?	❑ Yes	❑ No	
Major mental illness poorly controlled?	❑ Yes	❑ No	
Recent aggressive behavior problems?			

Ancillary Concerns			Date
Evidence of concerns with risk behaviors?	❑ Yes	❑ No	
Evidence of non-compliance with treatment or evaluations?	❑ Yes	❑ No	
Patient refused to sign contract?	❑ Yes	❑ No	
Other?	❑ Yes	❑ No	

Other information			Date
Liver biopsy approved?	❑ Yes	❑ No	

Liver biopsy results?		
Genotype		
HCV RNA results		
Type 1		
Type 2,3,4		

PATIENT CONTRACT CONCERNING
HEPATITIS C MEDICATION

ATTACH 2

1. I understand that treatment with therapy (interferon / pegylated interferon / ribavirin) may cause flu-like symptoms (fever, chills, headache, aching muscles and or joints, rapid pulse, nausea, vomiting, general feeling of being "rundown"). It may also cause fatigue, hair loss, bone marrow suppression, apathy, irritability, depression, suicidal Ideation, and changes in my thinking processes. Tolerance to these side effects may develop within a few weeks, or may persist. For some patients the side effects may necessitate stopping treatment.

2. I understand some of the side effects can be lessened by taking motrin as needed for symptom management, drinking at least 64 ounces of water/day, pacing my activities and my rest, and maintaining a healthy diet. I understand I am expected to follow these suggestions as necessary to help with any side effects.

3. I understand that one of the medications in this therapy, interferon, is by injections (shots). Pegylated interferon injections will be given once a week. I agree to be consistent in coming in for these injections.

4. I agree to periodic health evaluations including blood tests to monitor my overall health, side effects of the medicine, and to monitor treatment.

5. I understand that treatment will be required for at least a 24-week period. I understand that depending on the type of virus I have, the length of treatment and the terms of this contract may extend to 48 weeks; for a possible total of 72 weeks of medication, lab work, and provider checkups.

6. I understand this therapy can cause severe birth defects. I understand that it is extremely important and absolutely required that I do not become pregnant, or father a baby!!! If female, I agree to have a pregnancy test prior to starting treatment, and to have monthly pregnancy tests. (Only women who have had a hysterectomy are exempt from this requirement). If male, I will ensure that birth control measures are used. I understand that if I or my partner become pregnant, this therapy for Hepatitis C will be discontinued, I will be counseled about pregnancy termination, and I will assume all liability for any complications and/or birth defects.

7. I will abstain from any medication not prescribed for me or approved in writing for me to purchase from the canteen during the evaluation or the course of this treatment. I understand failure to do so can result in discontinuing this treatment.

8. I agree that I will not drink any beverage or medicine containing alcohol during my evaluation or course of this treatment. If I fail to follow this requirement, I will not be considered a candidate for this therapy, and therapy may be discontinued or not started until I have completed chemical dependency treatment.

9. I understand I may be requested to participate in chemical dependency treatment prior to starting this treatment.

10. I will abstain from all illegal substances, including but not limited to, IV drug use and inhaled drugs, during the evaluation or course of this treatment. If I fail to follow this requirement, I will not be considered a candidate for this therapy and therapy may be discontinued or not started until I have completed chemical dependency treatment.

11. I will submit to random urine drug tests prior to and during treatment, if my provider requests it. If I refuse, I will not be considered a candidate for this treatment.

12. I understand if my drug screen checks are positive during the course of this treatment, treatment may be discontinued until I have completed chemical dependency treatment.

14. I will not participate in tattooing during the course of this treatment. I understand if I do, treatment may be discontinued.

15. I understand if I do not come in for my medication as prescribed to treat my Hepatitis C, therapy may be discontinued.

16. I understand that the medications to treat Hepatitis C may make me feel angry and irritable, but that controlling my behavior is my responsibilty and taking this medication will not excuse any misconduct.

17. Finally, I understand that this therapy may not cure my disease and that even without treatment I could maintain good health.

Patient Signature _____

Date _____

Witness _____
(Health Services provider who conducted informed consent)

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